DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

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WARNING LETTER
ONPLDS- 03-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Anthony Costello
President and CEO
Optimum Nutrition
600 North Commerce St.
Aurora, Illinois 60504

Dear Mr. Costello:

The Food and Drug Administration (FDA) has reviewed the label for your Protein Diet™ Bar. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

This product is misbranded because the label bears the claims "Very Low Carbohydrate" and "enjoy the low-carbohydrate goodness" which are not authorized by regulation or the Act (21 U.S.C.343(r)(1)(A)). Although there is no regulation that would authorize the types of claims set out above for carbohydrates, your client may declare the amount (e.g., grams) of carbohydrates in a serving of this bar provided the statement does not imply that there is a little of the nutrient in the product (*See* 21 C.F.R. 101.13(i)(3)).

The label bears the statement "The product contains Glycerol. Glycerol is not a carbohydrate but has a caloric value of 4.32 calories per gram." It is not clear from this statement whether glycerol is included in the declaration of "Total Carbohydrates." We advise that glycerol must be included in the value declared for "Total Carbohydrates."

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements, (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Compliance
and Enforcement
Office Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition